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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/580,448 | 05/23/2006 | Jonathan Hughes | BT/3-22351/A/PCT | 4204 |

324 7590 09/08/2008

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| EXAMINER |
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AFREMOVA, VERA

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| ART UNIT | PAPER NUMBER |
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1657

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| MAIL DATE | DELIVERY MODE |
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09/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/580,448 | Applicant(s) HUGHES ET AL. | |
| | Examiner Vera Afremova | Art Unit 1657 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) 2-16 and 19-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/30/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' election of the group I (claim 1) in the reply filed on 6/02/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 1 is under examination in the instant office action.

Claims 2-16 and 19-31 have withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 6/02/2008.

Applicants' intention to request the rejoinder is noted. However, it is further noted that some of the withdrawn claims contain claims directed to several other non-elected products (enzymes, "improved" cell preparations and/or products-by-process) that do not have the identical final structures and final characterization as the elected product which is strain NCIMB 41164 and, therefore, they will not meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Further, withdrawn process claims that are not commensurate in scope with an elected allowable product claim will not be rejoined. See MPEP § 821.04(b). Furthermore, the issue(s) of double patenting might also exist.

Specification

The disclosure is objected to because of the following informalities:

1. As provided in 37 CFR 1.77(b), the specification of a utility application should include the particular sections in order with the section heading.

2. The current address of the depository collection is missing (page 7).

Appropriate correction(s) are required.

Claim Objections

Claim 1 is objected to because of the following informalities: The Latin name of microorganisms should be italicized. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims as written, do not sufficiently distinguish over nucleic acids, proteins, cells and antibodies as they exist naturally because the claims do not particularly point out any naturally occurring differences between the claimed products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 393, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of inventor. e.g., by insertion of “An isolated” as taught on page 7, line 22, of specification. See MPEP 2105.

Claim Rejections - 35 USC § 112

Indefinite

Claim 1 is rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 recites “a mutant” of strain NCIMB 41164. The specification does not provide definitions and/or characterization of the mutant as intended. Thus, the properties of the mutant as claimed are uncertain. The metes and bounds of the claim as drawn to a mutant cannot be determined. It is suggested to delete phrase “mutant thereof”.

Deposit

Claim 1 is rejected under 35 U.S.C. 112, *first paragraph*, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific microorganism *Rhodococcus rhodochrous* NCIMB 41164. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public.

The objection and accompanying rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and

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registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

Because NCIMB has acquired the status of an International Depository in accordance to the Budapest Treaty, a declaration stating that all restrictions will be irrevocably removed upon issuance of the patent will overcome this rejection.

Please, also provide deposit receipt of the claimed strain for the record.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 5,089,411 (Yamada et al).

Claim is directed to an isolated *Rhodococcus rhodochrous* strain NCIMB 41164 or its “mutant”.

US 5,089,411 (Yamada et al) discloses an isolated *Rhodococcus rhodochrous* strain J-1 (FERM BP-1478) and its various subcultures on various media or “mutant” that produce nitrile hydratase.

The referenced microorganism J-1 appears to be identical to the presently claimed strain and is considered to anticipate the claimed microorganism since it belongs to the same species of *Rhodococcus rhodochrous*, and, thus, it possesses the same identifying characteristics as the applicants’ strain NCIMB 41164. Consequently, the claimed strain NCIMB 41164 appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced strain and to its subcultures with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced strain J-1 and its subcultures are likely inherently possess the same characteristics of the claimed strain and “mutant thereof” particularly in view of the similar characteristics which they have been shown to share such as assignment to the same species and expression of nitrile hydratase. Thus, the claimed strain and/or “mutant thereof” would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Therefore, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

August 28, 2008

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/
Primary Examiner, Art Unit 1657